

Application No. 10/786,866

Reply to Office Action

*AMENDMENTS TO THE CLAIMS*

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Original) A method of treating a cellular proliferative disease, comprising administering to a mammalian host a pharmaceutical composition comprising:
  - (a) a therapeutically effective amount of liposomal vinorelbine also comprising cardiolipin, and
  - (b) a pharmaceutically acceptable excipient.
2. (Currently Amended) The method of claim 1, wherein the liposomal vinorelbine has an encapsulation ~~efficiency~~ efficiency of at least about 80%.
3. (Original) The method of claim 1, wherein the liposomal vinorelbine further includes  $\alpha$ -tocopherol.
4. (Original) The method of claim 1, wherein said mammalian host is a human.
5. (Original) The method of claim 1, wherein said cardiolipin is selected from the group consisting of natural cardiolipin and synthetic cardiolipin.
6. (Original) The method of claim 1, wherein said liposome bears a negative charge.
7. (Original) The method of claim 1, wherein said liposome bears a positive charge.
8. (Original) The method of claim 1, wherein said liposome is neutral.
9. (Original) The method of claim 1, wherein at least a portion of said vinorelbine is complexed with cardiolipin.
10. (Original) The method of claim 1, wherein said liposomes are a mixture of multilamellar vesicles and unilamellar vesicles.

Application No. 10/786,866

Reply to Office Action

11. (Original) The method of claim 1, wherein said pharmaceutical composition further comprises one or more therapeutic agents other than vinorelbine.
12. (Original) The method of claim 11, wherein one or more of said agents is an antineoplastic, antifungal or antibiotic agent.
13. (Original) A therapeutic composition comprising liposomal vinorelbine comprising a first liposome forming material comprising cardiolipin and a second liposome forming material.
14. (Original) The composition of claim 13, wherein the liposomal vinorelbine has an encapsulation efficiency of at least about 80%.
15. (Original) The composition of claim 13, which further includes  $\alpha$ -tocopherol.
16. (Original) The composition of claim 13, wherein a portion of said cardiolipin is complexed with said vinorelbine.
17. (Original) The composition of claim 13, wherein said liposome entrapped vinorelbine comprises vesicles having a diameter of about 5 $\mu$ m or less.
18. (Original) The composition of claim 13, wherein said liposome entrapped vinorelbine comprises vesicles having a diameter of about 1 $\mu$ m or less.
19. (Original) The composition of claim 13, wherein said liposome entrapped vinorelbine comprises vesicles having a diameter of about 0.5  $\mu$ m or less.
20. (Original) The composition of claim 13, wherein said liposome entrapped vinorelbine comprises vesicles having a diameter of about 0.1  $\mu$ m or less.

Application No. 10/786,866

Reply to Office Action

21. (Currently Amended) the composition of claim 13, wherein said second liposome-forming material is a lipid selected from the group consisting of phosphatidylcholine, cholesterol, ~~α-tocopherol~~, dipalmitoyl phosphatidylcholine and phosphatidyl serine.
22. (Currently Amended) The composition of any of claims 1-13, wherein said cardiolipin is selected from the group consisting of natural cardiolipin and synthetic cardiolipin.
23. (Original) The composition of claim 13, wherein said liposome bears a negative charge.
24. (Original) The composition of claim 13, wherein said liposome bears a positive charge.
25. (Original) The composition of claim 13, wherein said liposome is neutral.
26. (Original) The composition of claim 13, wherein said liposome is a mixture of multilamellar vesicles and unilamellar vesicles.
27. (Currently Amended) The composition of ~~claims~~ claim 13, wherein said pharmaceutical composition further comprises one or more therapeutic agents other than vinorelbine.
28. (Original) The composition of claim 27, wherein one or more of said agents is an antineoplastic, antifungal or antibiotic agent.
29. (Original) The composition of claim 13, further comprising one or more pharmaceutically acceptable excipients.
30. (Original) The composition of claim 29, wherein one or more of said excipients enhances shelf-life of the composition.

Application No. 10/786,866

Reply to Office Action

31. (Original) The composition of claim 29, wherein one or more of said excipients improves the stability of the composition.
32. (Original) The composition of claim 29, wherein one or more of said excipients is a sugar.
33. (Original) The composition of claim 32, wherein the sugar is selected from the group consisting of trehalose, maltose, sucrose, glucose, lactose and dextran.
34. (Original) The composition of claim 32 wherein the sugar is trehalose.
35. (Original) The composition of claim 32 wherein the sugar is sucrose.
36. (Original) The composition of claim 32 wherein the sugar is an aminoglycoside.
37. (Original) The composition of claim 36 wherein the aminoglycoside is streptomycin.
38. (Original) The composition of claim 36 wherein the aminoglycoside is dihydrostreptomycin.
39. (Original) The composition of claim 13 in dehydrated form.
40. (Original) The composition of claim 38, which is lyophilized.
41. (Original) The composition of claim 13, which is stable for up to about 12 months at between about 2° C and about 8°C.
42. (Original) A method for the treatment of mammalian cancer comprising administering a therapeutically effective amount of the composition of claim 13 to a patient in need thereof.

Application No. 10/786,866

Reply to Office Action

43. (Original) A method for the treatment of mammalian cancer comprising administering a therapeutically effective amount of the composition of claim 27 to a patient in need thereof.
44. (Original) The method of claim 42, wherein the patient is human.
45. (Original) The method of claim 43, wherein the patient is human.